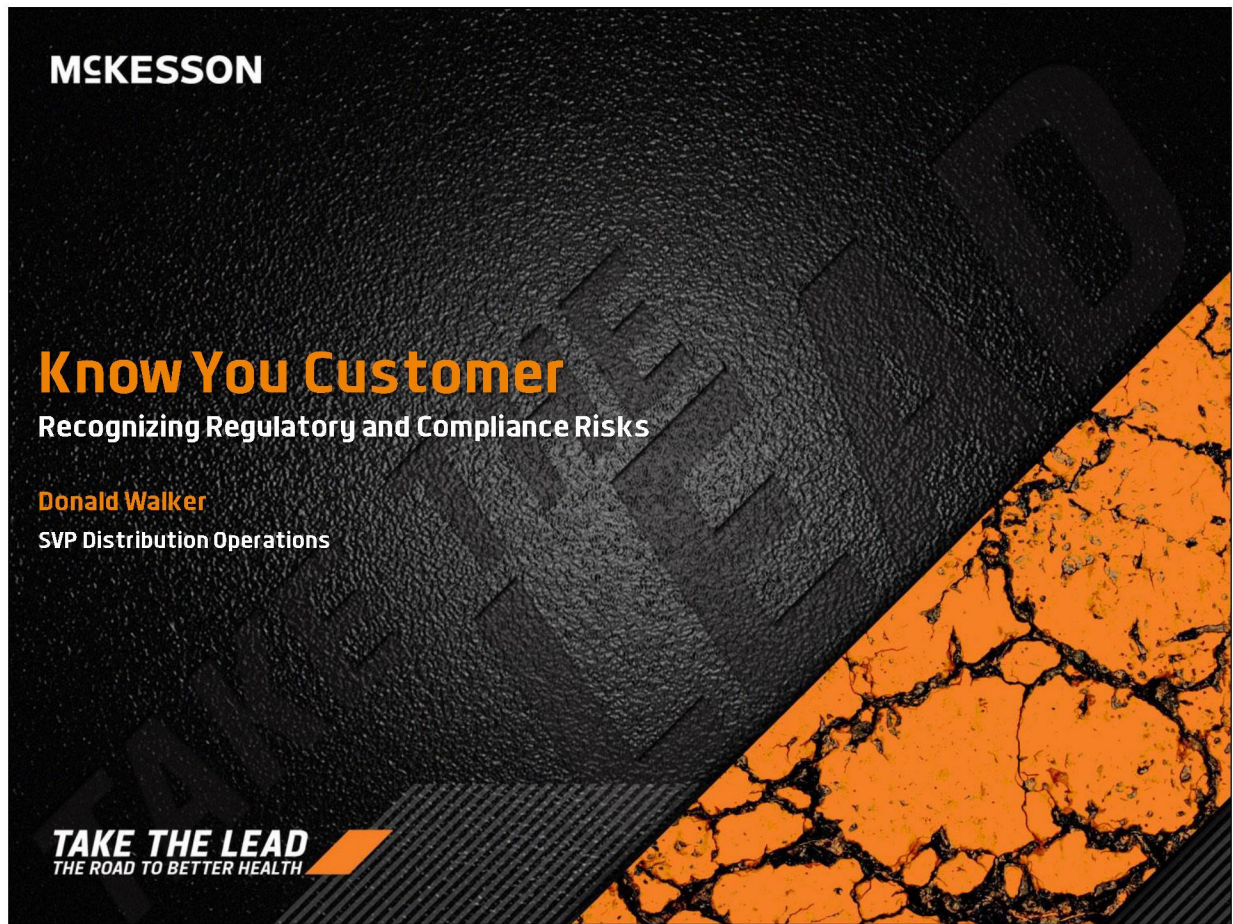

From: Walker, Donald [/O=MCKESSON/OU=NORTH AMERICA/CN=RECIPIENTS/CN=743A9CA9]
Sent: 5/2/2012 3:11:46 PM
To: Gustin, Dave [dave.gustin@mckesson.com]; McDonald, Tom [tom.mcdonald@mckesson.com]; de Gutierrez-Mahoney, Bill [bill.mahoney@mckesson.com]; Oriente, Michael [michael.oriente@mckesson.com]; Jonas, Tracy [tracy.jonas@mckesson.com]; Hilliard, Gary [gary.hilliard@mckesson.com]; Russell, Bruce [bruce.russell@mckesson.com]
Subject: Know Your Customer

On Monday I will be making a presentation to the ISMC sales force at NSC around Know Your Customer. This is intended to be an awareness awakening session that we as a regulatory team will follow –up on during the upcoming year. I only have a half hour so the material is high level. Please take a look at the deck attached and provide any feedback on points I may be missing. I need this back to me as soon as you can

Thanks

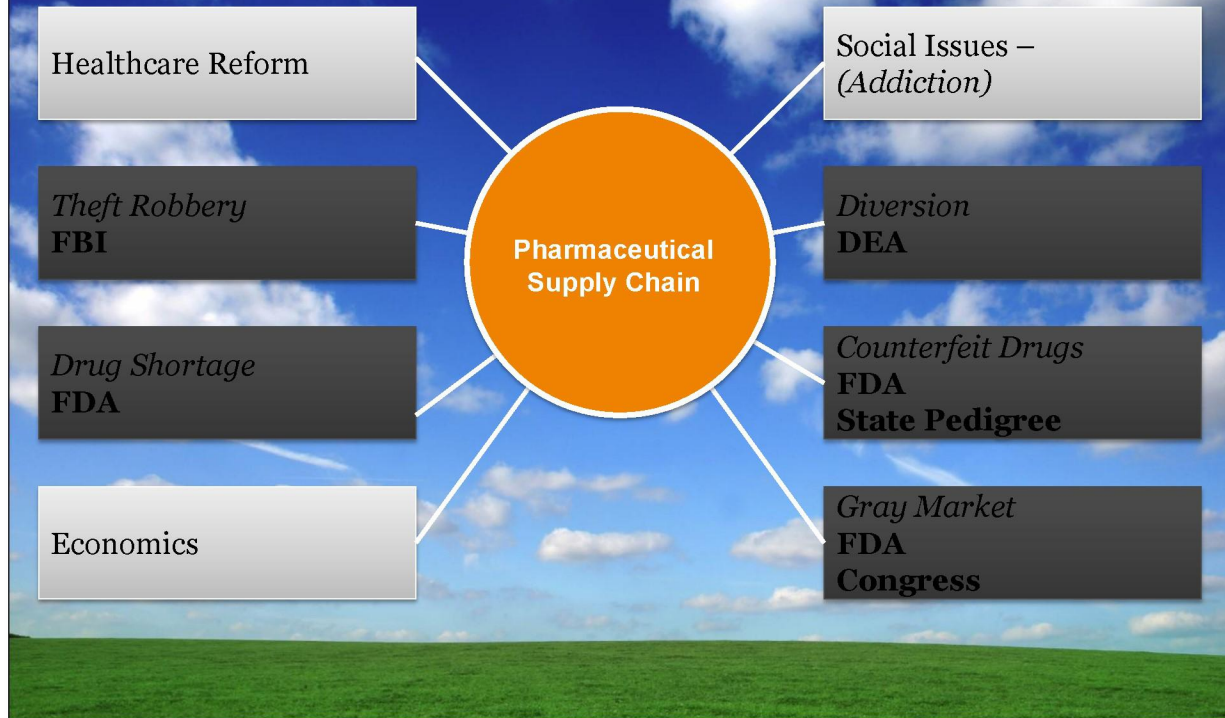
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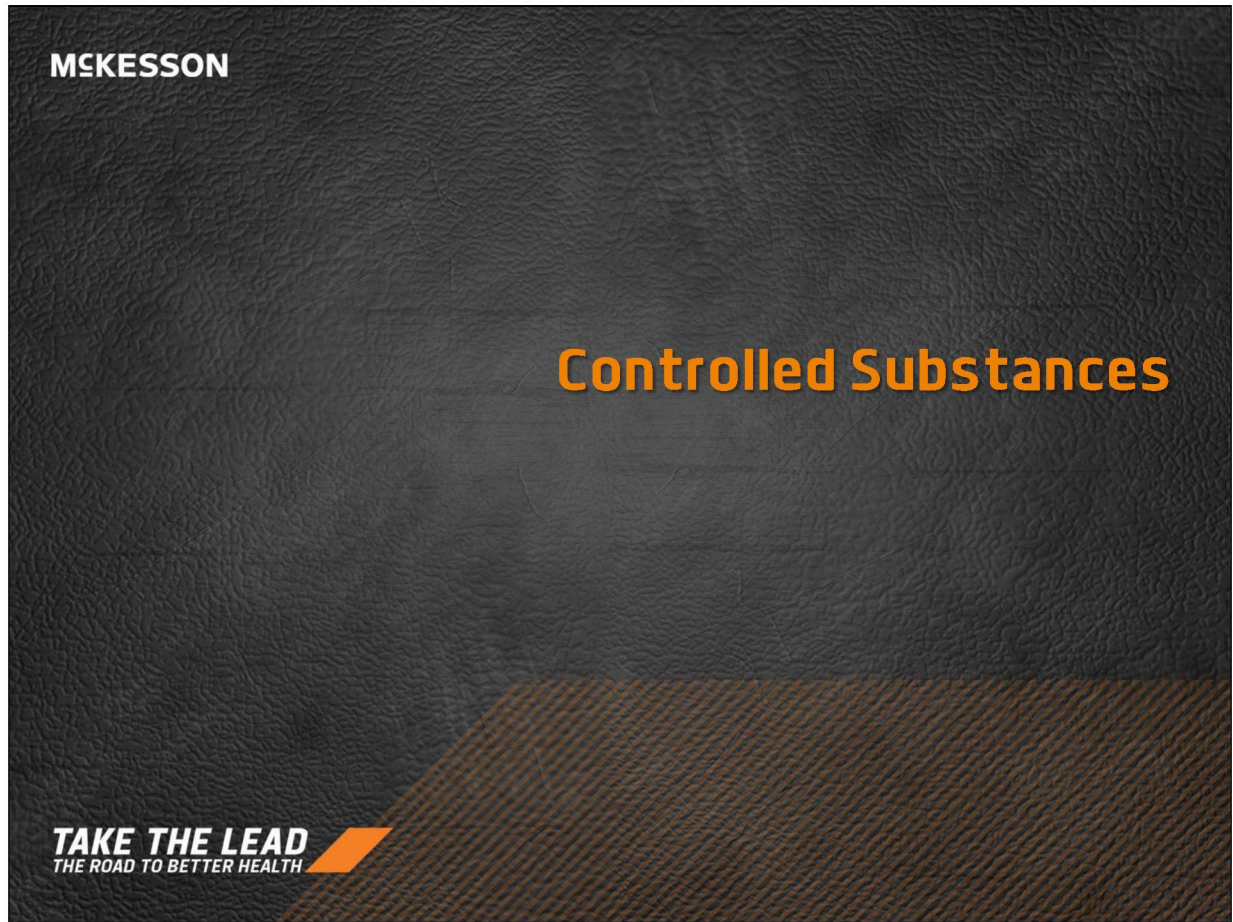
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EXHIBIT
P-12814_00001



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Government Focus





Government's View of the Problem

Alarming rate of increase of prescription drug abuse beginning approximately five years ago, especially hydrocodone (Vicodin) and opioid pain drugs (Oxycontin and Oxycodone)

- CDC currently classifies prescription drug abuse as an epidemic
- 27,000 died from prescription drug overdoses in 2007, a five fold increase since 1990
- During the same period ten fold increase in medical use of painkillers such as oxycodone and hydrocodone
- Today number of overdose deaths involving prescription pain medication exceeds deaths from heroin and cocaine combined
- In some states death from prescription painkiller overdoses surpass those from traffic accidents

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How the DEA Sees It

“The illicit pain clinics, the pharmacies that fill their scripts, and the wholesale distributors who supply pharmacies without appropriate due diligence -----
---, ***have caused, and continue to cause***, millions of dosage units of oxycodone and other controlled substances to be diverted and pose an imminent threat to the public health and safety.

Joseph Rannazzisi
Deputy Assistant Administrator
DEA Office of Diversion Control

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DEA Registrants

Know your customer and your customer's customer

Monitor the distribution of controlled substances

- ▶ May require understanding of order/prescribing patterns

Have systems in place to block or restrict suspicious orders

Report to DEA suspicious orders

Regulatory Burden

“Legitimate medical, scientific and industrial channels”

21 U.S.C 823 (b) (1)

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License Suspension Case Study

DEA Allegations Supporting Suspension

- Volume > 2 million doses per year
- Cash Payments: 42% - 58% Oxycodone paid in cash – 7% “normal”
- Increases in Volume > 200% increase
- No store visits to pharmacies in question
- What Distributor should have known
 - Pharmacies posed risk for diversion
 - Significant increases without due diligence
 - Should have recognized pharmacies explanation inadequate
 - Inadequate response should have prompted distributor to look further
 - Site visit would have revealed inconsistencies

Implications

- Court has upheld DEA's position
- Manufacturers are now conducting more rigorous Suspicious Order Monitoring
- Having a prescription from a doctor does not absolve a pharmacy
- As supply chain tightens
 - Increase in theft/robbery
 - Move to other controlled substances

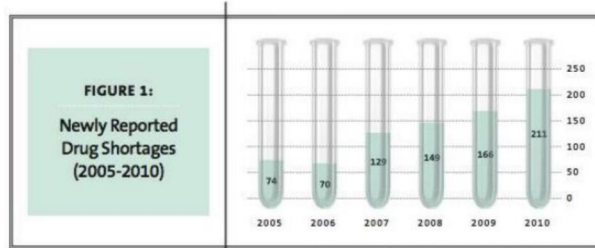
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Drug Shortage and The Gray Market

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Drug Shortage

- Number of prescription drugs in short supply tripled since 2005
- Publicity and awareness ramped up in 2011
 - Premier Whitepaper
- Executive Order 13588 – (10/31/11) – President Obama directs reduction of drug shortages



Source: Drug Information Service, University of Utah, 2010

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Drug Shortage



Gray Market

- Short supply items end up on a market at 300-400% price increase to customers
- ▶ Difficult to track until product surfaces in market
- ▶ Isolated incidents → Highly publicized

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Your Role in Knowing Your Customer

Prospective Customers:

- **Understand pharmacy business model**
 - % of business (scripts filled) that are controlled substances
 - Volume of critical drugs – Oxycodone, Hydrocodone, Alprazolam
 - Percent cash sales for controlled drugs
 - Pain clinics as a source of prescriptions
 - Screening process (if any) for controlled substance sale
 - Out of area scripts – average pharmacy serves 5-7 mile radius
 - Does pharmacy resell product – act as a wholesaler
- **Observe**
 - Store activity and patient profiles
 - Volume of controls relative to demographics

Your Role in Knowing Your Customer

Current Customers:

- **Recognizing Changes in Pharmacy's Business**
 - Regular increases in purchases of controlled substances
 - Drugs of Abuse
 - Increase purchases in items that may be
 - In short supply
 - Not consistent with prior purchases
 - Not consistent with community pharmacy
 - Changes in cash percentage for scripts filled
 - New niches pharmacy caters to
- **Observe and ask**
 - New business sources such as new doctors
 - Look for changes in profile of patients
 - Association with pain clinics

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Your Role in Knowing Your Customer

- Think compliance in your customer interaction
- Ask questions
- Seek advice and support
- Keep in mind Risk vs. Reward

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